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II

(Non-legislative acts)

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2021/471**of 17 March 2021****on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) and repealing Decision (CFSP) 2020/1826 (ATALANTA/2/2021)**

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Joint Action 2008/851/CFSP of 10 November 2008 on a European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Pursuant to Article 6(1) of Joint Action 2008/851/CFSP, the Council authorised the Political and Security Committee (PSC) to take the relevant decisions on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast ('Atalanta').
- (2) On 1 December 2020, the PSC adopted Decision (CFSP) 2020/1826 ⁽²⁾ appointing Captain Diogo ARROTEIA as EU Force Commander for Atalanta.
- (3) The EU Operation Commander has recommended the appointment of Captain Luca Pasquale ESPOSITO as the new EU Force Commander as from 17 March 2021. The Italian authorities have indicated that Captain Luca Pasquale ESPOSITO will be promoted to Rear Admiral upon his appointment as EU Force Commander.
- (4) On 9 March 2021, the EU Military Committee supported that recommendation.
- (5) Decision (CFSP) 2020/1826 should therefore be repealed.
- (6) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and the implementation of decisions and actions of the Union which have defence implications,

⁽¹⁾ OJ L 301, 12.11.2008, p. 33.

⁽²⁾ Political and Security Committee Decision (CFSP) 2020/1826 of 1 December 2020 on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) and repealing Decision (CFSP) 2020/895 (ATALANTA/3/2020) (OJ L 406, 3.12.2020, p. 60).

HAS ADOPTED THIS DECISION:

Article 1

Rear Admiral Luca Pasquale ESPOSITO is hereby appointed EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) as from 17 March 2021.

Article 2

Decision (CFSP) 2020/1826 is hereby repealed.

Article 3

This Decision shall enter into force on the date of its adoption.

It shall apply from 17 March 2021.

Done at Brussels, 17 March 2021.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2021/472

of 17 March 2021

on a common approach to establish a systematic surveillance of SARS-CoV-2 and its variants in wastewaters in the EU

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) According to Article 168(7) of the Treaty on the Functioning of the European Union ⁽¹⁾, the 'definition of health policy', as well as the 'organisation and delivery of health services and medical care' remain a national power. Member States are therefore responsible for deciding on the strategies to track the presence of SARS-CoV-2 in their populations, taking into consideration their epidemiological and social situations.
- (2) As announced on 11 November 2020 ⁽²⁾, the Commission intends to propose the establishment of a Health Emergency Preparedness and Response Authority (HERA) that will strengthen the Union's preparedness and response capability for new and emerging cross-border threats to human health. HERA's mission will be to enable the Union and its Member States to rapidly deploy the most advanced medical and other counter measures in the event of a public health emergency, by covering the whole value chain from conception to distribution and use.
- (3) This year the Commission is launching several preparatory actions that will lay the groundwork for HERA and serve as a blueprint for the Union's long-term preparedness for public health emergencies. On 17 February 2021, the Commission adopted a European bio-defence preparedness plan 'HERA Incubator', which sets out a proposal for immediate action to prepare Europe against the increased threat of SARS-CoV-2 variants ⁽³⁾.
- (4) New virus variants are evolving and spreading in Europe and across the world. The higher transmissibility and propensity of some of them to cause more severe disease, constitute a threat to our response against the virus. It is therefore important to use all available means to detect these variants as soon as possible to provide appropriate and timely responses.
- (5) One of the action areas that HERA Incubator is to focus on is the swift detection of current and future SARS-CoV-2 variants of concern. Member States' experience in this area have shown that surveillance of SARS-CoV-2 and its variants in wastewaters can provide a cost effective, rapid and reliable source of information on the spread of SARS-CoV-2 in the population and that it can form a valuable part of an increased genomic and epidemiological surveillance.
- (6) Wastewater monitoring should be considered as a complementary and independent approach to COVID-19 surveillance and testing strategies. As highlighted in Commission Recommendation of 28 October 2020 on 'COVID-19 testing strategies, including the use of rapid antigen tests' ⁽⁴⁾, robust testing strategies and sufficient testing capacities are essential aspects of preparedness and response to COVID-19. As also highlighted in the Commission's Communication of 2 December 2020 on 'Staying safe from COVID-19 during winter' ⁽⁵⁾ and of 19 January 2021 on 'A united front to beat COVID-19' ⁽⁶⁾, testing remains a crucial element for monitoring,

⁽¹⁾ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF>

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0724&qid=1605690513438>

⁽³⁾ COM(2021) 78 final, "A HERA Incubator: Anticipating together the threat of COVID-19 variants" https://ec.europa.eu/info/sites/info/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf

⁽⁴⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595>

⁽⁵⁾ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2020:786:FIN>

⁽⁶⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:35:FIN>

containing and mitigating the COVID-19 pandemic. Therefore, national testing strategies need to be urgently updated to take into account new variants, as they are central to COVID-19 control strategies. Surveillance of SARS-CoV-2 in wastewater can provide important complementary and independent information to public health decision-making process in the context of the ongoing COVID-19 pandemic. As a consequence, waste water monitoring needs to be included more systematically in the national testing strategies for the detection of the SARS-CoV-2 virus.

- (7) On 30 November 2020, the World Health Organization (WHO) organised an expert consultation on public health needs related to the surveillance of SARS-CoV-2 in wastewater ⁽⁷⁾, concluding that the surveillance of SARS-CoV-2 in wastewater can provide important complementary and independent information to public health authorities. It is, however, not a replacement for existing COVID-19 testing approaches and strategies. Wastewater surveillance is a tool to observe trends and not an absolute means to draw conclusions about the prevalence of COVID-19 in the population. It can serve different purposes at different stages of an epidemic.
- (8) More specifically, wastewater surveillance can be used for preventive or early warning purposes, as virus detection in wastewater should be taken as a signal of the possible (re-)emergence of the pandemic. Similarly, results indicating the absence of the virus in wastewater could indicate that the contributing population zone can be considered at a lower risk. An analysis of trends in results is also valuable for monitoring the effectiveness of measures put in place to curb virus transmission. Monitoring trends of viral concentration of SARS-CoV-2 variants in wastewater can therefore inform preparedness and response measures.
- (9) It is therefore critical that Member States put in place effective wastewater surveillance systems ensuring that relevant data are promptly provided to competent health authorities. Experience shows that setting up a new wastewater surveillance system can be achieved within a maximum of six months, as wastewater operators are used to monitoring different parameters in their installations.
- (10) Common methods for sampling, measurement and analysis should be made available and used in practice to ensure that the data collected is reliable and comparable.
- (11) It is crucial to support the sharing of best practice between Member States, but also with third countries that may not readily have access to data from usual testing practices. To this end, it is important to encourage Member States to participate in the future European exchange platform.
- (12) If necessary, and to accelerate and support the deployment of the activities set out in this Recommendation, EU funds will be made available to support wastewater surveillance activities and to ensure a systematic analysis of the presence of variants in wastewaters. This will allow Member States to accelerate the deployment of wastewater monitoring and analysis, while ensuring a regular analysis of SARS-CoV-2 and its variants in wastewaters.
- (13) While the data collection infrastructure for wastewater monitoring focuses on the surveillance of SARS-CoV-2 in the context of the ongoing public health pandemic, putting in place the recommended surveillance system and procedures will also have an added value beyond SARS-CoV-2 surveillance. It will provide an early warning for future possible outbreaks of other pathogens of concern or threats from other pollutants of emerging concern.
- (14) In light of the ongoing review of Council Directive 91/271/EEC ⁽⁸⁾, it is important to gather information from Member States on their experience in monitoring health relevant parameters in their wastewaters. This could help identifying health-related relevant parameters to be regularly monitored in the wastewaters.

⁽⁷⁾ <https://apps.who.int/iris/bitstream/handle/10665/339487/WHO-EURO-2021-1965-41716-57097-eng.pdf>

⁽⁸⁾ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

- (15) This Recommendation is part of a set of COVID-19 measures adopted by the Commission as announced in its Communication on 'A common path to safe and sustained re-opening' of 17 March 2021. The actions encouraged by this Recommendation are to be construed in the context of the wider Union initiative, and will build on the best practice put in place by Member States and countries across the world. They also build on the findings of a Commission project on wastewater surveillance ⁽⁹⁾ and the outcomes of the WHO consultation on public health needs related to the surveillance of SARS-CoV-2 in wastewater ⁽¹⁰⁾.

HAS ADOPTED THIS RECOMMENDATION:

Purpose of the Recommendation

- (1) The purpose of the Recommendation is to support Member States in establishing wastewater surveillance systems across the Union as a complementary data collection and management tool of the COVID-19 pandemic, focusing on the emergence and spread of SARS-CoV-2 variants.
- (2) This Recommendation sets out guidance that Member States are encouraged to take on the more systematic use of wastewater monitoring and inclusion in national testing strategies.
- (3) In particular, it sets out guidance for Member States on the design and management of SARS-CoV-2 wastewater surveillance systems, and the rapid transmission of the data collected to the competent health authorities. It promotes minimum requirements for efficient wastewater surveillance strategies and the use of common methods for sampling, testing and data analysis. It supports the sharing of results and best practice through a European exchange platform.

Wastewater surveillance

- (4) Member States are strongly encouraged to put in place as soon as possible and no later than 1 October 2021 a national wastewater surveillance system targeted at data collection of SARS-CoV-2 and its variants in wastewaters.
- (5) The surveillance system should cover a significant part of the Member State's population. The monitoring system should include at least wastewaters from large cities with over 150 000 inhabitants, preferably with a minimum sampling frequency of two samples per week. When necessary, additional sampling sites may be selected either to cover a sufficient part of the population or to better understand virus circulation related to possible movements of population through different territories (e.g. touristic sites during the summer season).
- (6) The minimum sampling frequency and geographical coverage should be adapted according to the epidemiological situation:
 - (a) When the competent public health authorities assess that, based on the local epidemiological situation, the pandemic is not a risk to the local population, the minimum sampling frequency should be reduced to one sample per week;
 - (b) When the disease is only present in some parts of the territory the minimum sampling frequency should be either decreased or increased depending on local circumstances.

⁽⁹⁾ <https://ec.europa.eu/environment/water/water-urbanwaste/info/pdf/Waste%20Waters%20and%20Covid%2019%20MEMO.pdf>

⁽¹⁰⁾ <https://www.euro.who.int/en/health-topics/environment-and-health/water-and-sanitation/publications/2021/expert-consultation-on-public-health-needs-related-to-surveillance-of-sars-cov-2-in-wastewater-summary-report-virtual-meeting,-30-november-2020>

- (7) The samples should be taken at inlets to wastewater treatment plants or where relevant upstream at the wastewater collecting networks. The presence of SARS-CoV-2 virus and its variants should be regularly analysed, ideally twice a month.
- (8) When more specific information is required to better map the presence of the virus and its variants, including among vulnerable communities, additional timely sampling and analysis should be carried out in targeted locations of the wastewater collecting network that corresponds to the population centre of concern. The definition of the locations and of the sampling frequencies should be adapted to the local needs (e.g. main sewer catchments and sub-systems of interest connected for instance to parts of the cities, hospitals, schools, university campuses, airports, other transport hubs, retirement centres, prisons, etc.).
- (9) Member States should ensure that the results of the wastewater surveillance are promptly sent by electronic means to the competent public health authorities and then, to the European exchange platform when the platform will be operational. For early warning surveillance purposes, the results for each sample should be recorded as soon as possible and preferably no later than 48 hours following sample collection.
- (10) To ensure an appropriate interpretation of the results but also to adapt the surveillance system to public health needs, Member States are encouraged to put in place adequate structures involving health and wastewater competent authorities with the objective to merge and link relevant datasets and to coordinate the interpretation and communication of results.
- (11) Member States should pay particular attention to ethical considerations: wastewater surveillance is an integral part of public health surveillance and therefore should comply with the same ethical principles, as set out in the 2017 WHO guidelines on ethical issues in public health surveillance ⁽¹⁾.

Sampling and analysis methods

- (12) To ensure that sampling and analysis methods are comparable and reliable, Member States should ensure that:
 - (a) the samples are taken over a period of 24 hours, using a flow or time composite sampler and during dry periods where at all possible or corrected for the influence of meteorological events through normalisation using 24 hours wastewater flow during the time of sampling and population size of the sewershed to calculate virus loads per capita per day;
 - (b) analyses are carried out in laboratories operating appropriate RT-PCR methods under standard quality management conditions;
 - (c) variant detection is made based on of duly documented gene sequencing methods;
 - (d) laboratories participate in appropriate proficiency testing as organised by accredited providers and use, where available, (certified) reference materials;
 - (e) the specific quality standards in Annex are respected.

Support to Union coordination

- (13) Member States are encouraged to participate in the efforts made by the Commission, in close collaboration with the European Centre for Disease Prevention and Control (ECDC) and other Union agencies to ensure that best practices and results, enabling appropriate and timely public health responses, as well as interpretation or use of such results are shared. To this end, Member States are strongly encouraged to participate in a European exchange platform to be set up by the Commission and which will focus on:
 - (a) gathering and sharing best practices, from Member States and beyond;
 - (b) collecting results from wastewater surveillance activities;

⁽¹⁾ WHO guidelines on ethical issues in public health surveillance, <http://apps.who.int/iris/bitstream/10665/255721/1/9789241512657-eng.pdf?ua=1>

- (c) publishing and regularly updating sampling and analysis methods;
 - (d) creating a voluntary list of experts involved in waste water surveillance and disease prevention and control using wastewater surveillance;
 - (e) organising a collaborative environment, promoting the intercalibration of approaches and sharing best practices.
- (14) Member States are invited to send feedback on their experience in that field to support the work of the Commission to define relevant health-related parameters to be regularly monitored in wastewaters. In this context, a broader surveillance going beyond public health should be considered. Member States are encouraged, in particular, to inform on the results of the monitoring in wastewater of emerging pollutants, emerging pathogens, drugs, pharmaceuticals, micro plastics or, consumption of antimicrobials.

International dimension

- (15) Member States are strongly encouraged to:
- (a) share best practices at international level by promoting further harmonisation in the surveillance of SARS-CoV-2 in wastewater;
 - (b) assist third countries having limited access to other sources of information to track virus presence in their population through wastewater monitoring;
 - (c) foster permanent cooperation in close coordination with the WHO but also other advanced partners having put in place their own surveillance systems.

Reporting - sharing best practices

- (16) To coordinate the responses to this Recommendation, Member States are encouraged to designate by 1 April 2021 not more than two contact points – representing public health and wastewater competent authorities.
- (17) Member States are encouraged to report to the Commission by 15 May 2021 the actions taken under the present Recommendation.

Done at Brussels, 17 March 2021.

For the Commission
Virginijus SINKEVICIUS
Member of the Commission

ANNEX

Specific Quality standards**(1) Standards for PCR/Digital-PCR (polymerase chain reaction)**

- (a) Threshold cycle value of real-time polymerase chain reaction (RT-qPCR) should be below 40 to report a sample as positive either for qPCR (quantitative polymerase chain reaction) analysis or to use for sequencing.
- (b) Alternative quantification approaches to RT-qPCR (as digital polymerase chain reaction - dPCR) could be used provided that they achieve results equivalent to RT-qPCR and apply quality requirements equivalent to RT-qPCR.
- (c) All samples should be run at least in duplicates to avoid false positive or false negative results.
- (d) The analytical procedure of real-time polymerase chain reaction used should include adequate controls to assess at least the efficiency of the concentration/extraction steps and the absence of significant reaction inhibition.
- (e) Each run should include appropriate standards (at least 3 point serial dilutions in triplicate employing synthetic SARS-CoV-2 RNA) and positive and negative controls to determine if the PCR/qPCR run produced reliable results.
- (f) A quantification cycle (Cq) cut-off value for positive samples should be set [at] 5 cycles before the termination of the amplification protocol to avoid misattribution of late fluorescence signals.
- (g) A negative extraction control should be used to account for any contamination during the RNA extraction.

(2) Standards for Next Generation Sequencing

- (a) At least 1 million reads-per-sample should be generated and read length should be above 100 base pair ⁽¹⁾.
- (b) At least 3 genetic markers per variant should be reported for better characterization of mutations for High Throughput Sequencing analysis of wastewater.

(3) Standards for normalisation

- (a) Viral number of gene copies should be normalised by the population number served by the sewer system and using the wastewater flow for better comparability of measurements between different locations.
- (b) Additional normalisation controls using cross-assembly phage (c) or pepper mild mottle virus are recommended for this purpose.
- (c) If data for none of viruses referred to in point (b) can be obtained, alternative parameters could be used provided they deliver equivalent corrections for meteorological or other influences causing fluctuations of the viral load, which are not related to the pandemic such as precipitation or other meteorological effects.

⁽¹⁾ <https://www.ecdc.europa.eu/sites/default/files/documents/Sequencing-of-SARS-CoV-2-first-update.pdf>

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